Application No.: 10/598.073 Fernandez-Salas, E., et al., Botulinum Toxin Screening Assavs

#### REMARKS

# Related Applications

The Applicants would like to make the Examiner aware of the following parent or child patent applications of the present patent application (see Table 1). Applicants request that the Examiner review the file histories, including all submitted and cited art, Office Actions, and pending claims regarding these patent applications.

Table 1		
U.S. Patent Application No.	Filing Date	U.S. Patent No.
2008-0182799	July 31, 2008	_

### Amendments to the Claims

Claims 1-33 are pending. Claims 2, 3, 9-15 and 23-27 are withdrawn. The Applicant respectfully asks the Examiner to replace all prior versions and listings of claims in the present application with the listing of claims currently provided. Claim 1 was amended; withdrawn Claims 2, 3, 23, 24 and 25 were amended; Claims 21, 26, and 27 were canceled. The Applicant states that all amended claims do not add new subject matter to the present specification.

Amendment support for Claim 1 regarding a cell that is genetically engineered to express a nucleic acid molecule encoding an exogenous FGFR3 can be found throughout the specification at, e.g., ¶¶ 36, 73, 74 and 87.

Amendment support for Claim 2 can be found throughout the specification at, e.g., ¶¶ 55.

### Summary of Interview Pursuant to 37 C.F.R. § 1.133(b)

The Applicants wish to thank the Examiner for the telephone interview on May 11, 2009. Pending Claims 1-33 were discussed in view of the outstanding rejection alleging anticipation pursuant to 35 U.S.C. § 102(b) and obviousness pursuant to 35 U.S.C. § 103(a). The Examiner and Applicants agreed that the proposed amendment to Claim 1 was sufficient to Fernandez-Salas, E., et al., Botulinum Toxin Screening Assavs

overcome all pending rejections. The Examiner and Applicants further discussed withdrawn claims and there condition for allowance.

# Rejection Pursuant to 35 U.S.C. § 102(b) Anticipation

## Keller reference

The Examiner has rejected Claims 1, 4, 7, 16, 17, 18, 19, 22,28 and 29 as allegedly being anticipated under 35 U.S.C. § 102(b) over James E. Keller et al., Persistence of Botulinum Neurotoxin Action in Cultured Spinal Cord Cells, FEBS Lett, 456(1): 137-142 (1999), hereafter the "Keller reference." The Applicants respectfully ask for reconsideration under 37 C.F.R. § 1.116.

According to MPEP § 2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 632 (Fed. Cir. 1987). The Applicants respectfully submit that the Examiner has failed to make a prima facie case of anticipation because the Keller reference does not disclose each and every element set forth in the presently claimed method.

The presently claimed method is directed in part, towards a cell that is genetically engineered to express a nucleic acid molecule encoding an exogenous FGFR3.

The Keller reference discloses a cell-based assay to detect BoNT/A and BoNT/E activity by contacting primary dissociated fetal mouse spinal cord neurons with either BoNT/A or BoNT/E and detecting the presence or absence of SNAP-25 cleavage product by Western blot analysis. See e.g., Keller at p. 138, col. 1, ¶¶ 4-5; p. 138, col. 2, ¶ 3. The Keller reference relied on endogenously expressed FGFR3. Id. at abstract, lines 1-3; p. 138, col. 1, ¶ 5. This can also be inferred from the fact that at the time the Keller reference conducted its experiments, the identity of the BoNT/A receptor was unknown. As such, it would have been impossible for the Keller reference to use cells that were genetically engineered to express a nucleic acid molecule encoding an exogenous FGFR3 because they were not in possession of the required knowledge or an external source of genetic material encoding an FGFR3. As Fernandez-Salas, E., et al., Botulinum Toxin Screening Assavs

such, the Keller reference does not read on the presently claimed method the cells disclosed in this reference where not genetically engineered to express a nucleic acid molecule encoding an exogenous FGFR3. Thus, the Keller reference does not anticipate because it does not set forth each and every element set forth in the presently claimed method. Therefore, the Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) anticipation rejections against Claims 1, 4, 7, 16, 17, 18, 19, 22, 28 and 29.

# Rejection Pursuant to 35 U.S.C. § 103(a) Obviousness

The Examiner has rejected Claims 5, 6, 8, 20, 21, 30-33 as allegedly being anticipated under 35 U.S.C. § 102(e) over the Keller reference in view of Ester Fernandez-Salas et al., Cell-Based Fluorescence Resonance Energy Transfer (FRET) Assays For Clostridial Toxins, U.S. Patent 7.183.066, hereafter the "Fernandez-Salas patent." The Applicants respectfully ask for reconsideration under 37 C.F.R. § 1.116.

The Applicants respectfully submit that the presently claimed method is not obvious over the Keller reference in view of the Fernandez-Salas patent. Therefore, the Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) anticipation rejections against Claims 5, 6, 8, 20. 21, 30-33.

Application No.: 10/598,073 17596 (BOT)

Fernandez-Salas, E., et al., Botulinum Toxin Screening Assays

## CONCLUSION

For the above reasons the Applicants respectfully submit that the claims are in condition for allowance, and the Applicants respectfully urge the Examiner to issue a Notice to that effect. The Examiner is invited to call the undersigned agent if there are any questions.

Please use Deposit Account 01-0885 for the payment of any extension of time fees pursuant to 37 C.F.R. § 1.136 or any other fees due in connection with the current response.

Respectfully submitted,

/Dean G. Stathakis/

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